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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/757,415 | 01/09/2001 | Ming-Ming Zhou | 2459-1-002N | 6912 |
| 7590 09/16/2004 | | | EXAMINER | |
| Klauber & Jackson 411 Hackensack Avenue Hackensack, NJ 07601 | | | MARTINELL, JAMES | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,415

Applicant(s)

ZHOU ET AL.

Examiner

James Martinell

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/20/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election with traverse of the requirement for restriction in the response filed June 28, 2004 is acknowledged. The traversal is on the ground(s) that there is no undue burden of search for the claims of Groups XII, IV, VI, XIII, and XV. This is not found persuasive because the scope of Groups IV and VI differs from that of elected Group XII in that the claims of Groups IV and VI are broader in embracing polypeptides with conservative amino acid substitutions. Thus, the searches for these Groups are not co-extensive and would be an undue burden upon the resources of the USPTO. Claim 19 of Group XIII is independent and distinct from claim 18 of Group XII and the search of both Groups would be an undue burden because the mode of action of the compounds in the two methods differs. In claim 18, the compound is required to inhibit formation of the SNT/FGFR complex, while for claim 19, the compound need only inhibit an SNT/FGFR dependent cellular signaling pathway. The inhibition of the pathway need not inhibit the formation of the SNT/FGFR complex. Finally, the searches of Groups XII and XV are not coextensive because Group XV (claim 21) requires only potential binding and not inhibition of the formation of the SNT/FGFR complex, thus a search of both Groups XII and XV would result in an undue burden on the resources of the USPTO.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17 and 19-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement (in connection with the restriction of Groups IV, VI, XII, XIII, and XV) in the response filed June 28, 2004.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

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The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

The Brief Description of the Drawings (pages 11-14) discusses Figures 1-4 and 6 as being in color.

The disclosure is objected to because of the following informalities: The instant application does not comply with the Sequence Rules (see 37 CFR §§ 1.821-1.825 and MPEP 2421-2434) in that sequences without SEQ ID NOs appear in Figure 1. See especially 37 CFR § 1.821(d).

Appropriate correction is required.

Claim 18 is objected to because of the following informalities:

- (a) In claim 18, "comprising: comprising:" should be changed to "comprising:".
- (b) In claim 18, "computer modeling;;" should be changed to "computer modeling;".

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is vague, indefinite, and incomplete.

- (a) The recitation of "using the three-dimensional structure" is vague and indefinite because "using" is not a positive process step. Thus, the metes and bounds of the claim are not clear.
- (b) The recitation of "potential compound" is vague and indefinite because the instant application does not distinguish between a potential compound and a non-potential or actual compound.

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- (c) The recitation of "computer modeling" is vague and indefinite because the term is not defined in the application and there is no art-recognized meaning for the term. Thus, the metes and bounds of the claims are not clear.
- (d) The recitation of "using rational drug design" is vague and indefinite because "using" is not a positive process step. Thus, the metes and bounds of the claim are not clear. In addition, the recitation of "rational" is incomplete because the instant application does not distinguish rational drug design from irrational drug design. Rational drug design has no art-recognized definite meaning.
- (e) The recitation of "decrease in the binding affinity" is incomplete because the claim does not specifically recite that a decrease in SNT-FGFR binding is a comparison between binding in the presence of a particular compound and in the absence of a particular compound.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al (J. Biol. Chem. 273: 17987 (1998)) in view of applicants' admitted state of the prior art (*e.g.*, instant application, paragraph bridging pages 4-5). Xu et al teaches that the SNT PTB (*i.e.*, SEQ ID NO: 1, amino acids 11-140) binding domain of FGFR is amino acids 401-434. For example, see the paragraph bridging pages 17989-17990 indicating that this region of FGFR is both necessary and sufficient to binding. Additionally, Xu et al demonstrates that FGFR-1/SNT interaction is needed for receptor-induced SNT tyrosine phosphorylation (page 17990, first paragraph of "*Conclusions*" section). Amino acids 401-428 of FGFR are identical to SEQ ID NO: 3 (see Keifer et al, U.S. Patent No. 6,255,454 SEQ ID NO: 1, amino acids 401-428, cited here to establish the FGFR sequence). Applicants acknowledge computer modeling and 3-dimensional determination of polypeptides to be old (*e.g.*, see the paragraph bridging pages 4-5 of the instant application). It would have been obvious for one of ordinary skill in the art at the time the invention was made to create a 3-D model of the SNT PTB binding domain of FGFR-1 and SNT PTB in order to inhibit formation of the SNT/FGFR complex and thus the activity FGFR as disclosed in Xu et al by using the admittedly old molecular modeling methods. It would further have been obvious to "trim down" the FGFR-1 residues to the exact length of SEQ ID NO: 3 by step-wise deletion of amino acids from the region of amino acids 401-434 to amino acids 401-428.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631
9/10/04